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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,968	07/31/2003	John J. Rossi	1954-401	3645

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ROTHWELL, FIGG, ERNST & MANBECK, P.C.  
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SUITE 800  
WASHINGTON, DC 20005

EXAMINER
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SHIN, DANA H

ART UNIT	PAPER NUMBER
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1635

NOTIFICATION DATE	DELIVERY MODE
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08/03/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/630,968	<b>Applicant(s)</b> ROSSI ET AL.	
	<b>Examiner</b> Dana Shin	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2007 and 10 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

This Office action is in response to the communications filed on July 9, 2007 and July 10, 2007.

Currently, claims 1-23 are pending.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Arguments and Amendments***

#### **Withdrawn Rejections**

Any rejections not repeated in this Office action are hereby withdrawn.

#### **Maintained Rejections**

#### ***Claim Rejections - 35 USC § 103***

Claims 1-5 and 8-21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Paddison et al. (*Genes & Development*, 16:948-958, 2002), in view of Tuschl (*Nature Biotechnology*, 20:446-448, 2002), Yu et al. (*PNAS*, Applicants' IDS citation AH, filed on November 19, 2003), Livache et al. (U.S. 5795715, 1998, also Applicant's IDS citation filed on

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August 15, 2005), and Jones et al. (*Nature*, 344:793-794, 1990) for the reasons of record as set forth in the Office action mailed on January 9, 2007 and for the reasons stated below.

Applicant's arguments filed on July 9, 2007 have been fully considered but they are not persuasive. In support of applicant's argument that the cited references are not "prior" art, applicant filed the declaration under 37 CFR 1.131; however, the declaration is ineffective to overcome the prior art references. The evidence, "APPENDIX A", submitted on July 10, 2007 is insufficient to establish a conception of the invention prior to the effective date of the Paddison et al., Tuschl, and Yu et al. references. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897).

The earliest filing date claimed and granted in the instant case is August 1, 2002, and the earliest publication date of prior art is April, 2002. Applicant declares that the claimed invention was conceived of and reduced to practice prior to April 2002. Contrary to applicant's declaration, nowhere in the submitted "APPENDIX A" is the concept of the claimed "loop sequence" disclosed.

Accordingly, the declaration under 37 CFR 1.131 and the evidence are ineffective to overcome the prior art references and therefore claims 1-5 and 8-21 remain rejected under 35 U.S.C. 103(a).

Claims 6-7 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Tuschl and Livache et al., as applied to claims 1-5 and 8-18 above, and further in view of Jeng et al. (*JBC*, 267:19306-19312, 1990) for the reasons of record as set forth in the Office action mailed on January 9, 2007 and for the reasons stated below.

Applicant's arguments filed on July 9, 2007 have been fully considered but they are not persuasive. Applicant argues that the rejection is improper because claim 1 was not rejected over Tuschl and Livache et al. since claim 1 was not rejected over these two references alone. Contrary to applicant's argument, the present claim rejection is applied only to claims 6 and 7 and does not include claim 1, and therefore, the instant rejection is technically correct. Further, claims 6-7 are properly rejected under Tuschl and Livache et al. in view of Jeng et al., because the combination of the three references teaches the instant claims. In support of applicant's argument that the cited references are not "prior" art, applicant filed the declaration under 37 CFR 1.131; however, the declaration is ineffective to overcome the prior art references. The evidence, "APPENDIX A", submitted on July 10, 2007 is insufficient to establish a conception of the invention prior to the effective date of the Tuschl reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897).

The earliest filing date claimed and granted in the instant case is August 1, 2002, and the publication date for Tuschl reference is May, 2002. Applicant declares that the claimed invention was conceived of and reduced to practice prior to April 2002. Contrary to applicant's declaration,

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nowhere in the submitted "APPENDIX A" is the concept of the claimed "loop sequence" or 4-5 "deoxyadenosines" disclosed.

Accordingly, the declaration under 37 CFR 1.131 and the evidence are ineffective to overcome the prior art references and therefore claims 6-7 remain rejected under 35 U.S.C. 103(a).

Claims 22-23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al. (*Nature Biotechnology*, May 2002, 20:505-508, applicant's citation No. AG, IDS filed on November 19, 2003) in view of Livache et al. (U.S. 5,795,715, also Applicant's IDS citation filed on August 15, 2005) for the reasons of record as set forth in the Office action mailed on January 9, 2007 and for the reasons stated below.

Applicant's arguments filed on July 9, 2007 have been fully considered but they are not persuasive. In support of applicant's argument that the cited references are not "prior" art, applicant filed the declaration under 37 CFR 1.131; however, the declaration is ineffective to overcome the prior art references. The evidence, "APPENDIX A", submitted on July 10, 2007 is insufficient to establish a conception of the invention prior to the effective date of the Paul et al. reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897).

The earliest filing date claimed and granted in the instant case is August 1, 2002, and the publication date for Paul et al. reference is May, 2002. Applicant declares that the claimed invention was conceived of and reduced to practice prior to April 2002. Contrary to applicant's declaration, nowhere in the submitted "APPENDIX A" is the concept of the claimed "loop sequence", "two or more different siRNA expression cassettes", or "different siRNA encoding gene and a different promoter" disclosed.

Accordingly, the declaration under 37 CFR 1.131 and the evidence are ineffective to overcome the prior art references and therefore claims 22-23 remain rejected under 35 U.S.C. 103(a).

### ***Conclusion***

All pending claims remain rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin  
Examiner  
Art Unit 1635

/J. E. Angell/  
Primary Examiner  
Art Unit 1635